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| APPLICATION NO.                                                                                                           | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO.       | CONFIRMATION NO.       |
|---------------------------------------------------------------------------------------------------------------------------|-------------|----------------------|---------------------------|------------------------|
| 10/804,360                                                                                                                | 03/19/2004  | Roger Farnholtz      | 1001.1690102              | 9216                   |
| 28075 7590 09/21/2007<br>CROMPTON, SEAGER & TUFTE, LLC<br>1221 NICOLLET AVENUE<br>SUITE 800<br>MINNEAPOLIS, MN 55403-2420 |             |                      | EXAMINER<br>BHATIA, AARTI |                        |
|                                                                                                                           |             |                      | ART UNIT<br>3709          | PAPER NUMBER           |
|                                                                                                                           |             |                      | MAIL DATE<br>09/21/2007   | DELIVERY MODE<br>PAPER |

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

## Office Action Summary

Application No.

10/804,360

Applicant(s)

FARNHOLTZ, ROGER

Examiner

Aarti Bhatia

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 19-41 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 19-41 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date 8/16/04.
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_.
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_.

### **DETAILED ACTION**

This is the initial Office action based on the 10/804,360 application filed on March 19, 2004, which is a continuation of the 09/863152 application filed on May 22, 2001, now US Patent 6,716,207. Claims 1-18 as originally filed were cancelled by applicant, amended claims 19-41 are currently pending and have been considered below.

#### ***Specification***

1. The disclosure is objected to because of the following informalities:

In the amendment to the specification, line 2 recites "U.S. Application Serial No. 09/863,152 filed May 22, 2001." should be updated to read -- U.S. Application Serial No. 09/863,152 filed May 22, 2001, now U.S. Patent No. 6,716,207. --. Appropriate correction is required.

#### ***Claim Rejections - 35 USC § 112***

2. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

3. Claims 19-41 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

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Claims 19-41 are drawn to a deflectable medical device shaft, where the shaft is covered by a sheath. There is no indication of a sheath in the parent application 09/863152, of which the current application is a continuation of. The examiner notes that the only mention of a sheath in the current application is in the claims and thus the sheath was newly added after the original filing.

### ***Double Patenting***

4. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

5. Claims 19-41 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 3, 4, 5, 6, 8, and 14 of U.S. Patent No. 6,716,207 in view of Heaven et al (U.S. Patent No. 5,318,528).

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With respect to claim 19, claims 1, 3, 4, 5, 6, 8, and 14 of Patent 6,716,206 teach a tubular proximal shaft section having a proximal end and a distal end (claim 1, lines 3-4); a plurality of slits defined in the proximal shaft section (claim 1, line 8); a distal shaft section attached to the proximal shaft section (claim 1, lines 3-4), the distal shaft section including a braid attached to the distal end of the proximal shaft section (claim 8, lines 1-2).

Patent 6,716, 206 fails to teach a sheath disposed over the proximal and distal shaft sections.

Heaven et al teaches a sheath disposed over the shaft of a steerable catheter (column 4, lines 54-56). It would be obvious to one having ordinary skill in the art at the time of the applicant's invention to modify the catheter of 6,716,206 with the sheath of Heaven. The sheath reduces resistance to movement and prevents materials from entering the side of the device (column 4, lines 56-62) thereby improving the performance of the steerable catheter.

With respect to claim 20, claims 1, 3, 4, 5, 6, 8, and 14 of Patent 6,716,206 teach the medical device of claim 19 (see above), wherein the distal shaft section is deflectable (claim 1, line 7).

With respect to claim 21, claims 1, 3, 4, 5, 6, 8, and 14 of Patent 6,716,206 teach the medical device of claim 19 (see above), wherein proximal shaft section has a longitudinal axis (claim 1, lines 7-8) and wherein the slits are arranged generally perpendicular to the longitudinal axis (claim 1, lines 8-9).

With respect to claim 22, claims 1, 3, 4, 5, 6, 8, and 14 of Patent 6,716,206 teach the medical device of claim 19 (see above), wherein the medical device has a transition in stiffness from the proximal shaft section to the distal shaft section (claim 1, lines 5-6).

With respect to claim 23, claims 1, 3, 4, 5, 6, 8, and 14 of Patent 6,716,206 teach the medical device of claim 19 (see above), wherein a greater number of slits are disposed near the distal end of the proximal shaft section than near the proximal end of the proximal shaft section (claim 3, lines 2-3).

With respect to claim 24, claims 1, 3, 4, 5, 6, 8, and 14 of Patent 6,716,206 teach the medical device of claim 19 (see above), wherein the number of slits per unit length is greater near the distal end of the proximal shaft section than near the proximal end of the proximal shaft section (claim 4, lines 2-3).

With respect to claim 25, claims 1, 3, 5, 6, 8, and 14 of Patent 6,716,206 teach the medical device of claim 19 (see above), wherein the slits have a first depth near the proximal end of the proximal shaft section and a second depth near the distal end of the proximal shaft section, and wherein the second depth is deeper than the first depth (claim 5, lines 2-4).

With respect to claim 26, claims 1, 3, 4, 5, 6, 8, and 14 of Patent 6,716,206 teach the medical device of claim 19 (see above), wherein the proximal shaft section is a nickel-titanium alloy tube (claim 14, line 2).

With respect to claim 27, claims 1, 3, 4, 5, 6, 8, and 14 of Patent 6,716,206 teach the medical device of claim 19 (see above), wherein the braid partially overlaps with the distal end of the proximal shaft section (claim 8, lines 1-2).

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With respect to claim 28, claims 1, 3, 4, 5, 6, 8, and 14 of Patent 6,716,206 teach a proximal shaft portion having a proximal junction (claim 6, line 2) and a distal junction (claim 6, line 3); a plurality of slits defined in the proximal shaft portion (claim 1, line 8); a braid attached to the distal junction and extending distally therefrom (claim 8, lines 1-2).

Patent 6,716,206 fails to teach a sheath disposed over the proximal and distal shaft sections.

Heaven et al teaches a sheath disposed over the shaft of a steerable catheter (column 4, lines 54-56). It would be obvious to one having ordinary skill in the art at the time of the applicant's invention to modify the catheter of 6,716,206 with the sheath of Heaven. The sheath reduces resistance to movement and prevents materials from entering the side of the device (column 4, lines 56-62) thereby improving the performance of the steerable catheter.

With respect to claim 29, claims 1, 3, 4, 5, 6, 8, and 14 of Patent 6,716,206 teach the medical device of claim 28 (see above), wherein the braid defines a distal shaft portion (claim 8, lines 1-2), and wherein the distal shaft portion is deflectable (claim 1, line 7).

With respect to claim 30, claims 1, 3, 4, 5, 6, 8, and 14 of Patent 6,716,206 teach the medical device of claim 28 (see above), wherein the proximal shaft portion has a longitudinal axis (claim 1, lines 7-8) and wherein the slits are arranged generally perpendicular to the longitudinal axis (claim 1, lines 8-9).

With respect to claim 31, claims 1, 3, 4, 5, 6, 8, and 14 of Patent 6,716,206 teach the medical device of claim 28 (see above), wherein the braid defines a distal shaft portion (claim 8, lines 1-2), and wherein the medical device has a transition in stiffness from the proximal shaft portion to the distal shaft portion (claim 1, lines 5-6).

With respect to claim 32, claims 1, 3, 4, 5, 6, 8, and 14 of Patent 6,716,206 teach the medical device of claim 28 (see above), wherein a greater number of slits are disposed near the distal junction of the proximal shaft portion than near the proximal junction of the proximal shaft portion (claim 3, lines 2-3).

With respect to claim 33, claims 1, 3, 4, 5, 6, 8, and 14 of Patent 6,716,206 teach the medical device of claim 28 (see above), wherein the number of slits per unit length is greater near the distal junction of the proximal shaft portion than near the proximal junction of the proximal shaft portion (claim 4, lines 2-3).

With respect to claim 34, claims 1, 3, 4, 5, 6, 8, and 14 of Patent 6,716,206 teach the medical device of claim 28 (see above), wherein the slits have a first depth near the proximal junction of the proximal shaft portion and a second depth near the distal junction of the proximal shaft portion, and wherein the second depth is deeper than the first depth (claim 5, lines 2-4).

With respect to claim 35, claims 1, 3, 4, 5, 6, 8, and 14 of Patent 6,716,206 teach the medical device of claim 28 (see above), wherein the proximal shaft portion is a nickel-titanium alloy tube (claim 14, line 2).

With respect to claim 36, claims 1, 3, 4, 5, 6, 8, and 14 of Patent 6,716,206 teach the medical device of claim 28 (see above), wherein the braid partially overlaps with the



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distal junction of the proximal shaft portion (claim 8, lines 1-2).

With respect to claim 37, claims 1, 3, 4, 5, 6, 8, and 14 of Patent 6,716,206 teach a slotted tubular member (claim 1, lines 7-8) having a proximal end (claim 1, line 3), a distal end (claim 1, line 4), and a longitudinal axis (claim 1, lines 7-8); a braid attached to the distal end of the tubular member and extending distally therefrom (claim 8, lines 1-2).

Patent 6,716,206 fails to teach a sheath disposed the tubular member and the braid so as to define a catheter shaft.

Heaven et al teaches a sheath disposed over the shaft of a steerable catheter (column 4, lines 54-56). It would be obvious to one having ordinary skill in the art at the time of the applicant's invention to modify the catheter of 6,716,206 with the sheath of Heaven. The sheath reduces resistance to movement and prevents materials from entering the side of the device (column 4, lines 56-62) thereby improving the performance of the steerable catheter.

With respect to claim 38, claims 1, 3, 4, 5, 6, 8, and 14 of Patent 6,716,206 teach the medical device of claim 37 (see above), wherein the slots defined are arranged generally perpendicular to the longitudinal axis (claim 1, lines 8-9).

With respect to claim 39, claims 1, 3, 4, 5, 6, 8, and 14 of Patent 6,716,206 teach the medical device of claim 37 (see above), wherein the slots vary in number, location, frequency, size, or depth so that the tubular member varies in stiffness between the proximal end and the distal end (claim 1, lines 10-13).

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With respect to claim 40, claims 1, 3, 4, 5, 6, 8, and 14 of Patent 6,716,206 teach a catheter shaft including a proximal shaft portion (claim 1, line 3), and a distal shaft portion (claim 1, line 4); the proximal shaft portion having a proximal end, a distal end, a longitudinal axis (claim 1, lines 7-8), and a plurality of slots defined therein that are arranged generally perpendicular to the longitudinal axis (claim 1, lines 8-9); the distal shaft portion including a braid that is attached to and partially overlaps with the distal end of the proximal shaft portion and extends distally from the distal end of the proximal shaft portion (claim 8, lines 1-2).

Patent 6,716,206 fails to teach a sheath disposed over the catheter shaft.

Heaven et al teaches a sheath disposed over the shaft of a steerable catheter (column 4, lines 54-56). It would be obvious to one having ordinary skill in the art at the time of the applicant's invention to modify the catheter of 6,716,206 with the sheath of Heaven. The sheath reduces resistance to movement and prevents materials from entering the side of the device (column 4, lines 56-62) thereby improving the performance of the steerable catheter.

With respect to claim 41, claims 1, 3, 4, 5, 6, 8, and 14 of Patent 6,716,206 teach the medical device of claim 40 (see above), wherein the slots vary in number (claim 1, line 10), location (claim 1, line 10), frequency (claim 1, line 11), size (claim 1, line 12), or depth (claim 1, line 12), so that the proximal shaft portion varies in stiffness (claim 1, line 13), between the proximal end and the distal end (claim 1, lines 5-6).

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***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

6. Claims 19-22, 26, 29, 37, 38, 40 are rejected under 35 U.S.C. 103(a) as being unpatentable over Qin et al (US Patent 6,251,092) in view of Donadio III et al (US Patent 5,741,429), and in further view of Heaven et al (US Patent 5,318,528).

With respect to claim 19, Qin et al teach a tubular proximal shaft section having a proximal end and a distal end (column 6, lines 48-49), and a distal shaft section attached to the proximal shaft section (column 6, lines 48-49), and a braided metal shaft (column 2, line 51).

Qin fails to teach a shaft section containing slits, or a sheath over the shaft of the catheter.

Donadio III et al teach a plurality of slits for making a tube more flexible (abstract).

Heaven et al teaches a sheath disposed over the shaft of a steerable catheter (column 4, lines 54-56).

With respect to claim 20, Qin teaches a catheter wherein the distal shaft section is deflectable (column 2, line 27).

With respect to claim 21, Qin teaches that the proximal shaft section has a longitudinal axis (column 6, line 52).

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Donadio teaches that slits are arranged generally perpendicular to the longitudinal axis (figure 17 (52)).

With respect to claim 22, Qin teaches that there is a transition in stiffness from the proximal shaft section to the distal shaft section (claim 1, lines 5-6).

With respect to claim 26, Qin teaches a proximal shaft section to be a nickel-titanium alloy tube (NITINOL) (column 2, line 57).

With respect to claim 37, Qin teaches a metal braid attached to the distal end of the tubular member (column 2, lines 50-54).

Donadio III et al teach a slotted tubular member having a proximal end, a distal end, and a longitudinal axis (figure 17).

With respect to claim 38, Donadio III et al teach that the slots defined are arranged generally perpendicular to the longitudinal axis (figure 17 (52)).

With respect to claim 40, Qin teaches a catheter shaft including a proximal shaft portion, and a distal shaft portion; the proximal shaft portion having a proximal end, a distal end, a longitudinal axis (see above), and a the distal shaft portion including a braid that is attached to and partially overlaps with the distal end of the proximal shaft portion and extends distally from the distal end of the proximal shaft portion (see above).

Donadio III et al teach a plurality of slots defined therein that are arranged generally perpendicular to the longitudinal axis (figure 17, (52)).

Heaven et al teaches a sheath disposed over the shaft of a steerable catheter (column 4, lines 54-56).

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It would be obvious to one having ordinary skill in the art at the time of the applicant's invention to modify the catheter of Qin with the slits of Donadio III et al to increase flexibility in the catheter. Further, it would have been obvious to improve the catheter with the sheath of Heaven. The sheath reduces resistance to movement and prevents materials from entering the side of the device (column 4, lines 56-62) thereby improving the performance of the steerable catheter.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Aarti Bhatia whose telephone number is (571) 270-5033. The examiner can normally be reached on Monday-Thursday 7:30am -5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph Del Sole can be reached on (571) 272-1130. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

  
JOSEPH DEL SOLE  
SUPERVISORY PATENT EXAMINER

9/18/07

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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